91-1064

NUMBER _____

IN THE

UNITED STATES SUPREME COURT

OCTOBER TERM, 1991

NICK & BARBARA LOZIER

Petitioners

vs.

F. BRANTLEY SCOTT, JR., M.D.

Respondent

PETITION FOR WRIT OF CERTIORARI FOR THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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Arnold Anderson Vickery
COUNSEL FOR PETITIONER
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2929 Allen Parkway,
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QUESTIONS PRESENTED FOR REVIEW

1. Whether, as a matter of law, the District Court erred in holding that the standard for consent to a routine medical procedure or device, as developed in state common law, was the same as the standard for consent to participation in research involving "investigational devices," as set forth in 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27.

2. Whether, as a matter of law, a human subject's consent to participation in research involving "investigational devices," as set forth in 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27, must be in writing.

3. In the alternative, whether, as a matter of law, the provisions of federal law which mandate that a human subject consent in writing to participation in research involving "investigational devices," as set forth in 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27, preempt state law permitting oral consent to surgery.

4A. In the alternative, whether the District Court erred in refusing to admit into evidence the provisions of federal law mandating that a human subject consent in writing to participation in research involving "investigational devices," as set forth in 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-

50.27, where consent to such participation is a material issue in the lawsuit.

4B. Also in the alternative, whether the District Court erred in refusing to instruct the jury on the provisions of federal law mandating that a human subject consent in writing to participation in research involving "investigational devices," as set forth in 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27, where consent to such participation is a material issue in the lawsuit.

Certificate of Interested Persons

The undersigned counsel of record certifies that the following listed parties have an interest in the outcome of this case. These representations are made in order that the Justices of this Court may evaluate possible disqualification or recusal.

(1) Nick and Barbara Lozier, Plaintiffs/Petitioners;

(2) Arnold A. Vickery, of the firm of VICKERY, KILBRIDE, GILMORE & VICKERY, 2929 Allen Parkway, Suite 2770, Houston, Texas 77019 and Macon Cowles, Esq. of the firm, WILLIAMS, TRINE, GREENSTEIN & GRIFFITH, 1435 Arapahoe Avenue, Boulder, Colorado 80302, their attorneys.

(3) F. Brantley Scott, Jr., M.D., Defendant/Respondent;

(4) Robert Swift and Dan Brown of the firm of FULBRIGHT & JAWORSKI, 1301 McKinney Street, Houston, Texas 77010, counsel for Defendant.

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OTHER REPORTS OF OPINIONS

The only opinion that has been written in this lawsuit so far is that of the United States Court of Appeals for the Fifth Circuit. This opinion was unpublished, and Petitioners have provided a copy of the opinion in the Appendix.

GROUNDS FOR JURISDICTION OF THE UNITED STATES SUPREME COURT

The United States Court of Appeals for the Fifth Circuit delivered its opinion on July 19, 1991. The Fifth Circuit denied Petitioner's Motion for Rehearing on August 15, 1991.

This Court has jurisdiction of this Petition for Writ of Certiorari pursuant to 28 U.S.C. §1254(1).

CONSTITUTION, STATUTES AND REGULATIONS

The following Constitutional provision, statutes and regulations are involved in this case. Pursuant to Rule 14.1(f) of the Rules of the Supreme Court of the United States, Petitioners give only their citations, and set forth their text in the Appendix.

U.S. Const. art. VI, cl. 2.

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §360j(g) (1984).

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §360k (1984).

28 U.S.C. §1254(1)

21 C.F.R. §§ 50.1-50.27 (1980).

Medical Liability and Insurance Improvement Act of Texas, Tex.Rev.Civ.Stat.Ann. art. 4590i, §6.06.

STATEMENT OF THE CASE

A. Introduction

Nick and Barbara Lozier filed this lawsuit against Dr. F. Brantley Scott to recover personal injury damages for Dr. Scott's unauthorized insertion of an inflatable prosthesis into Nick Lozier's penis, which ultimately resulted in Mr. Lozier's total impotence. There was federal jurisdiction of their claims based on diversity of citizenship, 28 U.S.C. §1332.

The Loziers asserted three legal theories, two of which are at issue in this Petition for a Writ of Certiorari: (1) negligence based upon Dr. Scott's failure to obtain a written consent to implant the penile prosthesis from Nick Lozier, as mandated by 21 U.S.C. §360j(g) and the regulations promulgated thereunder, 21 C.F.R. §§50.20-50.27; and (2) battery. The District Court ruled against the Loziers on the negligence/informed consent theory,

first by denying their Motion for Partial Summary Judgment, and later in the context of Dr. Scott's Motion for Directed Verdict. Moreover, the District Court even refused to admit the federal regulations into evidence, except as limited impeachment of Dr. Scott, and gave the jury a limiting instruction.

The District Court allowed the Loziers to submit their battery theory to the jury, but instructed the jury that "[t]he law, however, does not require that consent to surgery be in writing." Without the benefit of the federal statute and regulations, the jury did not find that Dr. Scott had implanted the penile prosthesis without Nick Lozier's consent, and the District Court entered a take-nothing judgment against the Loziers based on the jury's verdict. The Court of Appeals for the Fifth Circuit affirmed the District Court in an unpublished opinion.

The Loziers now seek a Petition for Writ of Certiorari from this Court, pursuant to Rule 10.1(c) of the Rules of the Supreme Court of the United States. What is at stake is not only the fate of Nick and Barbara Lozier's lawsuit but also the viability of 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27 as protection for those who participate in experiments involving "investigational devices," inventions for which the FDA has granted an exemption from its usual regulatory requirements so that the inventors can explore the viability of their inventions for commercial licensing and use. If this Court adopts Dr. Scott's view -- that an experimental subject's consent to the use of such a device can be oral rather than written, as the statute and regulations provide -- it will thwart Congress' intent, and could seriously undermine the public health and safety that Congress sought to protect by

prescribing extensive disclosures, to be put in writing and signed by the subject.

The Loziers maintain that the written consent requirement of the federal statute and regulations must apply in the area of experimental medical devices, both as the duty component of the Loziers' negligence/informed consent theory and as the affirmative defense to their battery theory. Believing that the Courts below have misconstrued and misapplied 21 U.S.C §360j(g), and 21 C.F.R. §50.1, et seq., and that this Petition presents an important question of federal law, the Loziers now request this Court to effect the intent of Congress and hold that this statute and these regulations do indeed mean what they say.

B. **Factual Background**

The facts germane to this Petition for Writ of Certiorari are undisputed. See Admissions of Fact

contained in the Joint Pretrial Order, included in the Appendix. As a result of an automobile accident in 1953, Nick Lozier had problems with scar tissue blocking his urethra. In 1986, he consulted Dr. Ralph Hopkins in Lander, Wyoming, about his blockage problems. Unfortunately, Dr. Hopkins removed so much of the scar tissue that Nick Lozier was rendered incontinent. Tr. at Vol. 16, p. 21. After he became incontinent, Lozier also had periodic problems with functional impotence -- not surprising for a man who constantly dripped urine, even during intercourse. Tr. at Vol. 16, p. 30. Ultimately, Dr. Hopkins referred Lozier to Dr. F. Brantley Scott in Houston, Texas for treatment of his incontinence.

Dr. Scott was a world famous urologist who achieved fame not only as a physician but also as an inventor. Dr. Scott invented two devices (and subsequent improvements on those devices) which have been used

extensively in the treatment of two major urological problems: (i) an artificial urethral sphincter used to treat **incontinence**, and (ii) an inflatable penile prosthesis used to treat **impotence**, Tr. at Vol. 10, p. 43. Dr. Scott's name appears on various patents pertaining to these devices. Along with several other principals, Dr. Scott founded American Medical Systems ["AMS"] to manufacture and market some of these devices. Tr. at Vol. 10, p. 103.

Both Lozier and Dr. Scott agreed that Lozier came to Houston to obtain an implant of the urethral sphincter, in order to control the flow of his urine. Tr. at Vol. 16, p. 51 (Lozier), and Vol. 10, p. 108 (Dr. Scott). Lozier wanted the sphincter implant, and signed a **written informed consent** for the sphincter surgery. Dr. Scott successfully implanted the sphincter into Mr. Lozier's abdomen; Mr. Lozier has had no significant problems

resulting from the sphincter; and the sphincter is not at issue in this litigation.

Unfortunately, as Nick Lozier -- under general anesthesia -- was being wheeled into the operating room to receive the sphincter, the charge nurse pointed out to Dr. Scott that he had scheduled Mr. Lozier not only for the implantation of the sphincter, for which Mr. Lozier had signed a written consent form, but also for the implantation of a penile prosthesis, for which he had signed no such form.[1] Tr. at Vol. 10, p. 10 (Dr. Scott). Nonetheless, Dr. Scott made a unilateral, conscious decision to proceed with **both** surgeries, even though there was no written consent form for the penile implant. Tr. at Vol. 10, p. 10, 15 (Dr. Scott). There is no question that Dr. Scott was fully aware that Mr. Lozier had not signed

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[1] Mr. Lozier had discussed the possibility of a penile prosthesis with Dr. Scott, but had decided against it.

a written, informed consent for the implantation of the penile prosthesis prior to and during the surgery.

Furthermore, Dr. Scott proceeded with the penile implant with full knowledge that federal statutes and regulations **required** a written consent form signed by the patient for this type of device. The penile prosthesis at issue is called a Hydroflex. Before Nick Lozier's operation, Dr. Scott's company, AMS, had secured an Investigative Device Exemption from the Federal Food and Drug Administration ["FDA"] pursuant to 21 U.S.C. §360j(g) to implant the Hydroflex in 100 patients on an experimental basis. One of the purposes of the clinical trials was to determine the degree to which the Hydroflex could maintain rigidity in a man with a large penis. Px 53. Dr. Scott found the perfect subject for this aspect of the clinical trials in Nick Lozier, whom Dr. Scott has described as in a "class by himself." Tr. at Vol. 10, p. 58.

As the inventor of the Hydroflex device, a founder and officer of AMS, and the chief physician involved in the clinical experiments, Dr. Scott participated actively in AMS' request for FDA approval and even signed a written document promising the federal regulators that he would make sure that his patients gave their consent in the form and manner required by federal law. Px 2.

Furthermore, the surgical protocol for the Hydroflex device at St. Luke's Hospital, where Dr. Scott practiced, and elsewhere, required a detailed, written form. Tr. at Vol. 10, p. 29, 39-42 (Dr. Scott). Indeed, Dr. Scott **wrote** (or revised) the Informed Consent document to be used in the clinical trials. Px 7 is his letter with a copy of his revisions to the Informed Consent. Thus, Dr. Scott established a standard of disclosure for the "Hydroflex" clinical trials requiring written disclosure, but then failed to adhere to his own standard.

Despite the fact that Dr. Scott had invented the Hydroflex; despite the fact that he knew that it was an experimental device which he could use only because the FDA had granted an exception to its usual regulatory requirements, and which could not be licensed for commercial use until its clinical probation had ended; despite the fact that he was familiar with the written consent requirement of the federal statute and regulations concerning the implantation of this device in human subjects; despite the fact that he had helped write the Informed Consent form that was to be signed by the subjects in the clinical experiment phase; despite the fact that he had expressly promised the federal regulators that he would insure that he obtained written, informed consent as required by law before implanting the Hydroflex into any participant in the experiments; despite the fact that he had found in Nick Lozier a one-of-a-kind

subject, and that he had a direct financial incentive to pass quickly through the clinical trials so that he could reap the benefits of commercial licensing of the Hydroflex[2], both of which called his objectivity directly into question; and despite the fact that he knew that Nick Lozier had NOT signed the required Informed Consent form to participate in the experiment, Dr. Scott proceeded with his irreversible experiment, and implanted the Hydroflex in Nick Lozier's penis on January 24, 1984.

The penile implant was a disaster. It was extremely painful for Lozier. Tr. at Vol. 16, p. 54. It never worked properly. Tr. at Vol. 17, p. 67. Ultimately, Mr. Lozier

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[2] Although the District Court instructed the jury that "[t]he law, however, does not require that consent to surgery be in writing," essentially reducing the consent issue to a swearing match between a world-famous physician and a "country-boy type" with a ninth-grade education, the Court did not allow the jury to consider Dr. Scott's direct financial incentive to implant as many Hydroflexes as possible in assessing his credibility. After the Hydroflex clinical trials were completed, Dr. Scott sold his stock in AMS for over $5,000,000.00. Tr. at Vol 10, p. 177.

had to have it removed. Tr. at Vol. 16, p. 58. In all likelihood, the implantation of the Hydroflex device by Dr. Scott caused **irrevocable**, irreversible tissue damage, so that Lozier is now permanently, organically, impotent. See Tr. at Vol. 17, p. 91 (Mr. Lozier), Vol. 20, p. 35 (Mrs. Lozier).[3]

In his own defense, Dr. Scott testified that he had spoken to Mr. Lozier before the operation, and that Mr. Lozier had informed Dr. Scott that he wanted both the urethral sphincter and the penile implant. Tr. at Vol. 10, p. 12. Lozier maintained steadfastly that he did **not**

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[3] There was considerable dispute in the record concerning the degree to which Nick Lozier was impotent prior to the surgery by Dr. Scott. Both Loziers maintained that, although Nick did not maintain as full an erection as he had previously enjoyed, he was still able to consummate sexual intercourse to the mutual satisfaction of himself and his wife. Tr. at Vol. 17, p. 83; Vol. 20, p. 27. According to the definition of impotency used by all of the experts in this case, this meant that Lozier was **not** impotent, and, therefore, not even a candidate for the Hydroflex prosthesis. Tr. at Vol. 19, p. 75, 124 (Dr. Hopkins); Vol. 12, p. 455 (Dr. Scott); Vol. 7, p. 3 (Dr. Paulsen).

consent to implantation of the penile prosthesis, because he was not convinced that he needed it or wanted it. Tr. at Vol. 16, p. 48. Although the jury -- without the benefit of the federal regulations, tendered as Px 63, and the evidence of Dr. Scott's direct financial bias in implanting as many Hydroflexes as quickly as possible, but **with** the District Judge's instruction that consent could be oral -- did not find that Dr. Scott implanted the Hydroflex without Lozier's consent, the Loziers assert that the jury should have never even considered this issue. As a matter of law, 21 U.S.C §360j(g), and the regulations promulgated thereunder, Protection of Human Subjects, 21 C.F.R. §50.1, et seq., superseded the issue of consent to the use of experimental devices on human subjects. The Fifth Circuit erred in holding to the contrary.

ARGUMENT AND AUTHORITIES

A. Framing the Issue

Much as an antitrust litigant must first determine the relevant product and market, the first task in the case at bar is to determine the scope of the Loziers' assertions. Dr. Scott has successfully advanced the idea in the Courts below that:

> the issue in this case is whether Congress intended, by passage of the Federal Food, Drug and Cosmetic Act (FDCA), to compel the states to provide for civil tort recovery for any failure to document consent in writing.

Brief of Appellant F. Brantley Scott, Jr., M.D. in the United States Court of Appeals for the Fifth Circuit at 12. The Fifth Circuit adopted Dr. Scott's approach. Opinion at 5.

The Loziers have not made such a sweeping assertion in this case. First and foremost, the holding in this case does not apply to all medical negligence cases involving the issue of informed consent. The Hydroflex was a "device for investigational use" -- an experimental

device on probation until it had proven its worth and reliability in controlled, clinical tests. 21 U.S.C. §360j(g). Certainly, the analysis of how a subject must consent to the use of an experimental device on probation is vastly different than the analysis of how a patient may consent to the use of a proven device or a routine procedure in commercial use.

Second, the Loziers do not contend that the FDCA compels (or, for that matter, could compel) the State of Texas to enact a comprehensive scheme for civil tort recovery. Dr. Scott attempts to argue that, if a federal statute preempts state law, it must do so on a grand scale. This is not true. If a federal statute preempts state law, it need not preempt every facet of the preempted subject.

As any first-year law student could attest, a tort consists of a duty, breach of that duty, causation and damages. The Loziers do not argue that 21 U.S.C.

§360j(g) and 21 C.F.R. §50.1 et seq. establish the tort of negligence based on failure to obtain informed consent under Texas law, or define its elements. What 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27 do in this regard is **define the duty -- how one must obtain informed consent -- in the limited area of "Investigational Devices."** Likewise, concerning the Lozier's theory that Dr. Scott committed battery by implanting a Hydroflex in Nick Lozier's penis, the federal statute and regulations do not create the tort of battery in Texas, or alter the elements of or defenses to that tort. The federal statute and regulations do, however, define how one must consent to what would otherwise constitute a battery, where the tortfeasor commits the battery by implanting an "Investigational Device."

The Loziers and Dr. Scott have drawn the battle lines clearly. The Loziers assert that, when dealing with

"Investigational Devices," informed consent must be in writing, period. Dr. Scott asserts that the subject may give his informed consent orally.

B. **The Statutory Framework**

Congress amended the Food, Drug and Cosmetic Act ["FDCA"] in 1976 to confer authority on the FDA to regulate both drugs and medical devices. P.L. 94-295, 90 Stat. 574 (May 28, 1976)(codified at 21 U.S.C. §§301-92). Section 360j of the FDCA sets forth "[g]eneral provisions respecting control of devices intended for human use," and prescribes regulations applicable to such devices.

The statutory section at issue in this lawsuit, 21 U.S.C. §360j(g), provides an "[e]xemption for devices for investigational use," and exempts "investigational devices" from the usual regulatory requirements of the FDCA. In their stead, section 360j(g) prescribes its own regulatory requirements for "investigational devices" that are separate

from and more stringent than the requirements applicable to other devices regulated by the FDCA, based on the unproven nature of such devices.

> It is the purpose of [21 U.S.C. §360j(g)] to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

21 U.S.C. §360j(g)(1). Accordingly, Congress enacted section 360j(g) to encourage invention and innovation, but only to the extent consistent with public health and safety and with ethical standards.

The most important provision of 21 U.S.C. §360j(g) with regard to public health and safety and to ethical standards addresses the issue of informed consent. If citizens are to participate in experiments, the scientist must fully inform them as to the risks, and must obtain

their knowing consent. Congress mandated that the person applying for an investigative device exemption

> (D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, except [in life-threatening situations] . . .
>
> The determination required by subparagraph (D) shall be concurred in by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

21 U.S.C. §360j(g)(3).

The Regulations promulgated under 21 U.S.C. §360j(g) are set forth at 21 C.F.R. §50.1, et seq., under the general heading "PROTECTION OF HUMAN SUBJECTS." Subpart B -- Informed Consent of Human Subjects addresses the issue of informed consent, and specifically mandates that

> [e]xcept as provided in §56.109(c), informed consent **shall** be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative.

21 C.F.R. §50.27(a)[emphasis added].

There is no dispute that the Hydroflex penile prosthesis that Dr. Scott implanted in Nick Lozier on January 24, 1984 was an "Investigative Device" subject to the requirements of 21 U.S.C. §360j(g) and the Regulations promulgated thereunder. Likewise, there is no dispute that Nick Lozier never signed a written Informed Consent for the implantation of the Hydroflex.

Finally, the Loziers cite portions of the FDCA and the Regulations that provide some guidance on whether Congress intended to preempt state law regarding informed consent concerning investigative devices.

> **(a) General rule**. Except as provided in subsection (b), no State or political subdivision of a State may establish or

continue in effect with respect to a device intended for human use any requirement --

> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

(b) Exempt requirements. Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if --

> (1) the requirement is more stringent than a requirement under this Act which would be applicable to the device if an exemption were not in effect under this subsection; . . .

21 U.S.C. §360k[underlining added; boldface in original].

The regulations provide that:

> (c) The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require **additional** information to be disclosed for informed consent to be legally effective.

21 C.F.R. §50.25[emphasis added].

The clear message from these provisions is that Congress intended the federal statute and regulations to establish the minimum standard for informed consent concerning "investigational devices." If a State wishes to impose additional, more stringent requirements for informed consent to be legally binding, it can do so. However, a State cannot allow a human subject involved in research to consent to the use of an investigative device in any manner that does not meet the federally-imposed minimum standard. The Loziers assert that, under the Statute and Regulations, Nick Lozier could not legally

consent to the implantation of the Hydroflex except in writing.[4]

C. **A Subject Cannot Consent to the Use of an Investigative Device Governed by 21 U.S.C. §360j(g) Except in Writing**

The Loziers assert that 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27 set the minimum standard that any purported consent to the use of an "investigational device" must meet. To the extent that this minimum standard

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[4] Interestingly, Texas law also indicates that consent should be given in writing:

> **Manner of Disclosure**
>
> Section 6.06. Consent to medical care that appears on the panel's list requiring disclosure shall be considered effective under this subchapter if it is given in writing, signed by the patient or a person authorized to give the consent and by a competent witness, and if the written consent specifically states the risks and hazards that are involved in the medical care or surgical procedure in the form and to the degree required by the panel under Section 6.04 of this subchapter.

Tex.Rev.Civ.Stat.Ann. art. 4590i (Vernon Supp. 1991). Thus, the District Judge's instruction that "[t]he law, however, does not require that consent to surgery be in writing" appears all the more curious.

conflicts with state law, the federal statute and regulations would preempt any form of consent that falls below this standard (i.e. that is not in writing). In the case at bar, however, there is not necessarily a conflict. The District Judge simply assumed that consent under Texas common law, developed to analyze informed consent in the context of routine devices and procedures, was the same as consent to participation in research involving "investigational devices" as understood by 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27. In so doing, the District Judge equated apples and oranges -- or, more appropriately, apples and kumquats. This was entirely inappropriate. While oral consent may be perfectly acceptable in routine devices and procedures, it is certainly not acceptable when dealing with devices to which 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27 apply. The Loziers assert that, as a matter of law, the

federal statutes apply to consent to participate in research involving investigational devices, and state law applies to consent to routine matters. Accordingly, the District Court erred in refusing to apply the federal statute and regulations to the case at bar.

In the alternative, if the federal statute and regulations do conflict with state law regarding consent, the federal statute and regulations preempt state law with regard to investigational devices. To determine whether there is federal preemption of any particular subject, one must ascertain whether Congress intended to preempt state law on that subject.

There are three principal indications of preemption. First, Congress can expressly state that it intends to preempt state law. This method is sufficient, though not necessary, to demonstrate federal preemption. **International Paper Co. v. Ouellette**, 107 S.Ct. 805, 811

(1987). Second, courts may infer preemption "when the federal legislation is 'sufficiently comprehensive to make reasonable the inference that Congress "left no room" for supplementary state regulation.'" **Ibid.**(ultimately quoting **Rice v. Santa Fe Elevator Corp.**, 331 U.S. 218, 230 (1947)). Finally,

> [i]n addition to express or implied pre-emption, a state law also is invalid to the extent that it "actually conflicts with a . . . federal statute." **Ray v. Atlantic Richfield Co.**, 435 U.S. 151, 158, 98 S.Ct. 988, 994, 55 L.Ed.2d 179 (1978). Such a conflict will be found when the state law "'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" **Hillsborough County v. Automated Medical Laboratories, supra**, 471 U.S., at 713, 105 S.Ct., at ___ (quoting **Hines v. Davidowitz**, 312 U.S. 52, 67, 61 S.Ct. 399, 404, 85 L.Ed.2d 581 (1941).

Ouellette, 107 S.Ct., at 811. Under either the second or third types of preemption, 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27 supersede Texas state law to the extent that Texas law would permit a human subject to

consent orally to the use of an "investigational device" such as the Hydroflex.

Preemption is most obvious under the third, "conflict with state law" analysis. If Dr. Scott (and the District Court) is correct in his assertion that Nick Lozier could consent orally to the implantation of the Hydroflex -- at least as a defense to battery -- there is a blatant conflict with 21 C.F.R. §50.27(a), which mandates that consent be documented on an approved, written consent form.

Texas law allows a medical negligence plaintiff in Nick Lozier's position to recover under a theory of battery. The lead case in Texas unambiguously states the rule of law as follows:

> [A] surgeon is subject to liability for assault and battery where he operates without the consent of the patient or the person legally authorized to give such consent.

Gravis v. Physicians & Surgeons Hospital, 427 S.W.2d 310, 311 (Tex. 1968). Accord **Johnson v. Whitehurst**, 652 S.W.2d 441, 444 (Tex. App. -- Houston [1st Dist.] 1983, writ ref'd n.r.e.)("a doctor must secure the authority or consent of his patient in order to legally perform medical procedures."). Consent is an affirmative defense to battery. Likewise, it is clear that the purpose of 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20 - 50.27 is to protect human subjects from participation in experiments involving "investigational devices" until the scientist explains all the risks involved and allows the subject to see them in writing, reflect on them and physically consent to them by his/her signature. Did Congress intend Dr. Scott's proferred result: that oral consent to the implantation of an experimental device is adequate as a defense to battery, thereby depriving a plaintiff such as Nick Lozier of exactly the protection that Congress has afforded him?

Certainly not. Such a result would "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." **Ouellette**, 107 S.Ct., at 811.

This analysis is a fortiori true of the Loziers' negligence/lack of informed consent theory. Again, if oral consent could suffice, Dr. Scott would negate Congress' protection for human subjects like Nick Lozier in its entirety, rendering the express words of 21 U.S.C. §360j(g) and 21 C.F.R. §50.27(a) utterly meaningless.

In summary, the method that Congress chose to reach its goal of protecting public health and safety and upholding ethical standards in the area of "investigational devices" was to require a written consent form documenting informed consent. To allow oral consent where an "investigational device" is involved would frustrate Congress' intent. "A state law [] is preempted if it interferes with the methods by which the federal statute

was designed to reach [Congress'] goal." **Ouellette**, 107 S.Ct., at 813.

The Court could reach the same result using the "implied preemption" analysis. At first blush, it appears that 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20 - 50.27 are not "sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation." **Ouellette**, 107 S.Ct., at 811. This seems particularly true in light of the following language:

> The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.

21 C.F.R. §50.25(c). See also 21 U.S.C. §360k(b). However, the analysis must return to the intent of Congress: to establish the minimum standard for informed consent to the use of "investigational devices." In fact, Congress left no room for supplementary state regulation

of anything less than the federal standards for informed consent. See **Ouellette**, 107 S.Ct., at 810, 812 (Clean Water Act, 33 U.S.C. §1251 et seq., provision that allowed state in which a pollution source was located to adopt more stringent discharge limitations than those of the federal government was valid to preempt attempted application of the laws of adjacent states).

As the Loziers pointed out above, Dr. Scott has implied that a federal statute must set forth a comprehensive civil tort recovery scheme in order to preempt state law that overlaps the federal statute. This is simply untrue. Federal law can preempt certain provisions of state law, while leaving other provisions in force. See **Ouellette**, 107 S.Ct., at 814-15 (Vermont residents allowed to maintain nuisance action in federal court, sitting in Vermont, against company with pollution point source discharge in New York, despite provisions of

Clean Water Act; BUT Clean Water Act mandated that court apply substantive law of New York). Just as the plaintiffs in **Ouellette** were able to maintain their action in Vermont, with federal law supplying only the choice of law, the Loziers may maintain their action against Dr. Scott under Texas law, with federal law supplying only the standard for consent.

D. **Using a Federal Statute to Supply the Duty or the Defense for a State Tort Remedy is Entirely Consistent with Both Texas and Federal Law**

This Court has recognized that there can be circumstances where "'a breach of the duty imposed by the federal statute'", gives rise to state tort claims. **Merrell Dow Pharmaceutical, Inc. v. Thompson**, 478 U.S. 804, 106 S.Ct. 3229, 3236n.14 (1986)(quoting **Moore v. Chesapeake**

& Ohio R. Co., 291 U.S. at 214-15).[5] That is precisely the issue in this case.

This holding is entirely consistent with Texas law. Texas courts have long recognized that the breach of a statute, ordinance, or regulation is negligence per se so long as it is clear to the court that the plaintiff is a member of the class of persons for whom the law in question is designed to protect. **El Chico Corp. v. Poole,** 732 S.W.2d 306, 312 (Tex. 1987)(establishing per se liability for violation of alcoholic beverage code); **Nixon v. Mr. Property Mgt. Co.,** 690 S.W.2d 546, 549 (Tex. 1985). The Texas Court of Appeals in San Antonio has made it quite clear that the statute or regulation which establishes the duty can be **federal.** **Peek v. Oshman's Sporting Goods, Inc.,** 768 S.W.2d 841, 845 (Tex.App. -- San

---

[5] At a minimum, Dr. Scott's violation of 21 U.S.C. §360j(g) should "constitute a 'rebuttable presumption' or a 'proximate cause' under state law." **Merrell Dow**, 478 U.S. at 812, 106 S.Ct. at 3234.

Antonio, 1989, writ denied)(affirming summary judgment for defendant because no fact issue raised violation of federal firearms statute and implementing regulations, but specifically acknowledging that "we here recognize a standard of care imposed by statute").

CONCLUSION

For the reasons set forth above, Petitioners urge the Court to hold that, while oral consent to routine medical devices and procedures under state law may be acceptable, written consent pursuant to 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27 is required for a human subject to participate in research involving "investigational devices."

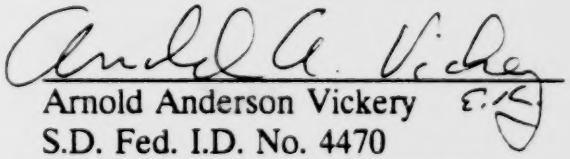
In the alternative, if the Court finds that there is a conflict between 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27 on the one hand, and state law permitting oral consent on the other, Petitioners urge the Court to

hold that the federal statute and regulations preempt state law concerning the method of giving consent to one's participation in experiments involving "investigational devices," as a matter of law.

In the alternative, Petitioners urge the Court to hold that the District Court could and should have at least admitted the regulations into evidence and given the jury appropriate instructions concerning the mandatory nature of these laws, and to remand the case on that basis.

Respectfully submitted

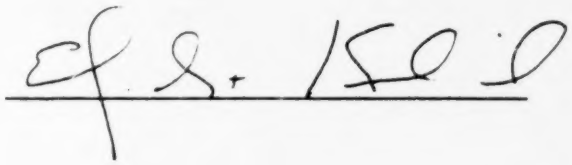
VICKERY, KILBRIDE, GILMORE
& VICKERY



Arnold Anderson Vickery
S.D. Fed. I.D. No. 4470
Texas State Bar No. 20571800
2929 Allen Parkway, Suite 2770
Houston, Texas 77019
(713) 526-0700

PROOF OF SERVICE
CERTIFICATE OF SERVICE

Pursuant to Rule 29.3 of the Rules of the Supreme Court of the United States, I certify that three copies of the Petition for Writ of Certiorari has been served on Robert J. Swift, FULBRIGHT & JAWORSKI, 1301 McKinney, Suite 5100, Houston, Texas 77010-3095 via first class postage prepaid, on this 13th day of November, 1991.



91-1064

NUMBER _____

IN THE

UNITED STATES SUPREME COURT

OCTOBER TERM, 1991

NICK & BARBARA LOZIER

Petitioners

vs.

F. BRANTLEY SCOTT, JR., M.D.

Respondent

PETITION FOR WRIT OF CERTIORARI FOR THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

APPENDIX

Arnold Anderson Vickery
COUNSEL FOR PETITIONER
VICKERY, KILBRIDE, GILMORE
& VICKERY
2929 Allen Parkway,
Suite 2770
Houston, Texas 77019
(713) 526-0700

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COUNSEL FOR PETITIONER
VICKERY, KILBRIDE, GILMORE
& VICKERY
2929 Allen Parkway,
Suite 2770
Houston, Texas 77019
(713) 526-0700

Table of Contents

14. Plaintiff's Exhibit 11

UNITED STATES COURT OF APPEALS

FOR THE FIFTH CIRCUIT

No. 90-2297

Nick Lozier and Barbara Lozier,

(Plaintiffs-Appellants)

v.

F. Brantley Scott, Jr., M.D.,

(Defendant-Appellee)

Appeals from the United States

District Court for the Southern

District of Texas

(July 19, 1991)

Before Reynaldo G. GARZA, HIGGINBOTHAM and DAVIS, Circuit Judges.

Per Curiam:[1]

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[1] Local Rule 47.5 provides: "The Publication of opinions that have no precedential value and merely decide particular cases on the basis of well-settled principles of law imposes needless expense on the public and burdens on the legal profession." Pursuant to that rule, the court has determined that this opinion should not be published.

Appellants complain about the trial court's choice of law, rulings on evidence and instructions to the jury. Finding no error, we affirm.

I. The Facts.

Nick and Barbara Lozier,[2] appellants, brought this action against Dr. Scott alleging battery, lack of informed consent and negligent presurgical work-up for implanting an experimental penile prosthesis. The case was brought under diversity jurisdiction.

As a result of an automobile accident in 1953, Lozier's urethra became severed which caused urinary retention, and problems would arise when he attempted to obtain an erection. In 1986 Lozier consulted Dr. Hopkins in Wyoming about his urinary blockage. Hopkins removed so much scar tissue that Lozier was left incontinent.

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[2] Though both Mr. and Mrs. Lozier are parties to this suit, when this opinion refers to "Lozier" it means Nick Lozier.

Hopkins recommended Lozier to appellee, Scott. Dr. Scott was well known not only as a urologist but as the inventor of both an artificial urethral sphincter used to treat incontinence and of an inflatable penile prosthesis used to treat impotence (the "Hydroflex"). In order to market these devises, Scott, along with others, founded American Medical Systems ("AMS").

Both Lozier and Scott agree Lozier came to Houston to get a urethral sphincter implanted. There is a signed written informed consent form for this procedure. Lozier asserts he never consented to the implantation of the Hydroflex, Scott claims he did. There never was, however, any signed informed consent form for the Hydroflex. In fact, Scott knew there was no written consent and that he was required to have such a consent as required by federal statutes and regulations.

The Hydroflex was an experimental device. The FDA granted permission to try the Hydroflex out on 100

patients. One of the main purposes was to determine the rigidity the Hydroflex could maintain in a man with a large penis. Lozier appears to have been a prime candidate for the procedure; Scott was so impressed he described Lozier as being in a "class by himself."

Once under anesthesia for the urethral sphincter, the charge nurse noticed there was no written consent for the Hydroflex procedure. Scott claims he did not want to perform the sphincter procedure and then endanger Lozier by putting him under again and believing there was consent, he made a notation in the medical chart that consent had been obtained. The sphincter procedure alleviated some of the problems with Lozier's incontinence. The Hydroflex, however, was a flop. The Hydroflex was extremely painful and never worked properly. It was subsequently removed and left Lozier permanently impotent. There is some dispute as to whether Lozier was impotent before the procedure. Both

Loziers claim before the procedure, though he could not obtain a full erection, a mutually satisfying sexual experience was possible; i.e. he could not be impotent according to the experts. On the other hand, Lozier filed an affidavit in his Wyoming state claim against Hopkins stating that the operation made him impotent.

The Loziers moved for partial summary judgment before trial and for a directed verdict during the trial based upon the federal statute and regulations. The informed consent charge was dropped because only a battery claim could lie on the facts. The judge limited the admission of the regulations which the Loziers claim helped prove their case. In the jury instructions, the judge only explained that Texas battery does not require written consent and completely ignored the federal statute and regulations. The jury found that Lozier had consented and therefore did not have to answer the rest of the

questions posed. The judge entered judgment in favor of Scott and the Loziers now appeal.

II. The Law.

Before we address the role the federal statute and regulations should play in this litigation, we must consider what claims were before the jury. Lozier complains that only battery and negligence in presurgical work-up were presented; he asserts the issue of informed consent should have been before the jury as well. Under Texas law, an informed-consent action sounds in negligence and is concerned with the adequacy of the physician,s disclosure to his patient. See Wison v. Scott, 412 S.W.2d 299, 302 (Tex. 1967). A battery claim, on the other hand, is an intentional tort for offensive or harmful contact; and consent is a defense. Restatement (Second) of Torts §§ 13, 49. Scott moved for a partial directed verdict on the issue of informed consent and it was granted after Lozier,s attorney agreed the claim should be dropped. Lozier now

argues that he had always objected to the partial directed verdict on the informed consent issue and that acquiescing in the final act of dismissal does not bar appeal. While Lozier may not have wanted the informed consent issue dropped, it is clear he went along with Scott's motion willingly. No burden is presented to a party by requiring him to object in such a situation.

Even assuming the issue of informed consent has been settled, Lozier still maintains that the trial judge erred by failing to charge the jury on 21 USC § 360j and 21 C.F.R. Part 50. Section 360j(g)(3) requires a doctor to ensure that consent is obtained, and 21 C.F.R. § 50.27 states that consent "shall be documented by use of a written consent form." (emphasis added). Since this language is clear and has been violated, the Loziers claim they are entitled to recover.

In order for the statute and regulations to apply, they must preempt Texas tort law. Congress provided a test for preemption:

> No State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-
>
> 1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> 2) which relates to safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 USC § 360k(a). This provision only preempts "different" "requirements" a State may attempt to implement. The statute and the regulation do not attempt to establish any sort of tort recovery; therefore, we must

look to Texas law and we find no requirement in Texas law that consent be in writing. See Gravis v. Physicians and Surgeons Hosp. of Alice, 427 S.W.2d 310, 311 (Tex. 1968).

Lozier also contends that, even if federal law does not preempt Texas battery principles, Texas statutory law incorporates the federal standards for what constitutes valid consent. The Texas Medical Liability and Insurance Improvement Act, Tex. Rev. Civ. Stat. Ann. art. 4590i (Vernon Supp. 1990), determines what type of disclosure is required according to how a drug or procedure are classified by the Texas Medical Disclosure Panel. Section 6.07(b) states that when the Panel has not made a determination either way regarding a duty to disclose about the medical care in question, the physician is "under the duty otherwise imposed by law." At the time this case arose, penal implantation had not been classified by the Panel, and therefore disclosure was under a "duty

otherwise imposed by law." Though the Loziers would have us look to the federal statute and regulations, the Texas Supreme Court has interpreted this duty "to be the duty imposed by section 6.02 of the act: to disclose all risks or hazards which could influence a reasonable person in making a decision to consent to the procedure." Peterson v. Shields, 652 S.W.2d 929, 931 (Tex. 1983). The trial court did not err when it refused to give the federal statute and regulations the force of law and hold Scott liable, and therefore, the jury permissibly found Scott not liable under the battery and negligence claims. Similarly, the trial court did not err when it told the jury "[t]he law, however, does not require that consent to surgery be in writing."

Lozier complains alternatively, that the trial judge should have allowed into evidence Plaintiff's Exhibit 63, which contained 21 C.F.R. Part 50. Though the trial judge allowed the federal regulations to be used to impeach

Scott,[3] she refused to allow it in for any other purpose. The court was concerned with the jury confusing the federal statute and regulation with the Texas law. The trial judge has discretion to exclude introduction of a federal regulation into evidence pursuant to Fed. R. Evid. 403. See United States v. Burton, 737 F.2d 439, 443 (5th Cir. 1984)(stating "that the judge remains the jury's source of information regarding the law. The Rule 403 balance, when struck by the district court in the first instance, will not be overturned on appeal absent an abuse of discretion."). Having found the trial judge properly excluded the federal statute and regulation, we furthermore find the trial judge did not abuse her discretion in refusing to admit Plaintiff's Exhibit 63 into evidence.

---

[3] Lozier's attorney thereby, was allowed to show the jury that Scott was aware of the federal regulation requiring a written informed consent. The attorney read § 50.27 to Scott in the presence of the jury and Scott admitted he had not complied.

The Loziers also argue the trial court erred by not admitting evidence of Scott's $5,000,000 profit from the sale of AMS. They argue this evidence would give rise to a very strong inference that Scott had a large financial incentive in completing the clinical trials of the Hydroflex as soon as possible and to recruit all eligible patients; this would help to impeach Scott,s position that he had Lozier's consent. We disagree with the Loziers. A trial judge's ruling on the admissibility of the evidence is generally reviewed for an abuse of discretion. Jon-T Chemicals, Inc. v. Freeport Chemicals, Inc., 704 F.2d 1412, 1417 (5th Cir. 1983). Because only battery and negligence of the presurgical work-up were before the jury, the only issues they had to decide was whether Lozier had consented,[4] and whether Scott's work-up was within the appropriate standard of care. Under the battery and

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[4] If there is consent, no battery exists. Moss v. Rishworth, 222 S.W. 225, 226 (Tex. Comm'n App. 1920, holding approved).

negligence theories, the information concerning Scott's profit from the sale of his AMS stock was not relevant. The trial judge stated that this evidence would be admitted for the purposes of an exemplary damages award if the jury first found gross negligence but none was found. The trial judge did not abuse her discretion.

III. Conclusion

The trial court did not err in its application of law and did not abuse its discretion in not admitting Plaintiff Exhibit 63 or evidence of Scott's profit from sale of his AMS stock. Accordingly, we AFFIRM the trial court's rulings.

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF TEXAS

HOUSTON DIVISION

CIVIL ACTION NO. H-86-381

NICK AND BARBARA LOZIER

Plaintiffs

VS.

F. BRANTLEY SCOTT, JR., M.D.

Defendant

ORDER

Pending before the Court is Plaintiffs' Motion for Partial Summary Judgment. Having considered the arguments of the parties and the applicable law, the Court is of the opinion that the Motion should be DENIED.

Accordingly, it is ORDERED, ADJUDGED and DECREED that the Motion be and hereby is DENIED.

The Clerk shall file this Order and provide a true copy to counsel for all parties.

DONE at Houston, Texas this 13th day of July, 1988.

Gabrielle K. McDonald

United States District Judge

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF TEXAS

HOUSTON DIVISION

CIVIL ACTION NO. H-86-381

CONSOLIDATED WITH

CIVIL ACTION NO. H-86-1958

NICK AND BARBARA LOZIER

Plaintiffs

VS.

F. BRANTLEY SCOTT, JR., M.D.

Defendant

FINAL JUDGMENT

Pursuant to the Verdict of the Jury dated January 26, 1990, it is hereby

ORDERED that judgment be entered in favor of Defendant; that Plaintiffs take nothing from Defendant; and that Defendant recover of the Plaintiffs his costs of court.

This is a **FINAL JUDGMENT.**

Signed this the 8th day of February, 1990.

Melinda Harmon

United States District Judge

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF TEXAS

HOUSTON DIVISION

CIVIL ACTION NO. H-86-381

NICK AND BARBARA LOZIER

Plaintiffs

VS.

F. BRANTLEY SCOTT, JR., M.D.

Defendant

ORDER

CAME ON TO BE HEARD this day the Motion for New Trial of Plaintiffs in the above-captioned and numbered cause, and the Court, having considered said Motion, is of the opinion that it is not meritorious and should be denied. It is therefore

ORDERED that Plaintiffs' Motion for New Trial is hereby in all things DENIED.

Signed this 4th day of April, 1990.

Melinda Harmon

United States District Judge

IN THE UNITED STATES COURT OF APPEALS

FOR THE FIFTH CIRCUIT

NO. 90-2297

NICK AND BARBARA LOZIER

Plaintiffs-Appellants,

VS.

F. BRANTLEY SCOTT, JR., M.D.

Defendant-Appellant

Appeal from the United States District Court for the Southern District of Texas

ON PETITION FOR REHEARING

August 15, 1991

Before GARZA, HIGGINBOTHAM and DAVIS, Circuit Judges.

PER CURIAM:

IT IS ORDERED that the petition for rehearing filed in the above entitled and numbered cause be and the same is hereby denied.

CLERK'S NOTE:

SEE FRAP AND LOCAL RULES 41 FOR STAY OF THE MANDATE

ENTERED FOR THE COURT:

_____

UNITED STATES CIRCUIT JUDGE

UNITED STATES CONSTITUTION

ARTICLE VI. -- MISCELLANEOUS PROVISIONS

Clause

1. Prior debts valid under Constitution.

2. Supreme law.

3. Oath of Office.

Clause 1. Prior debts valid under Constitution.

All Debts contracted and Engagements entered into, before the Adoption of this Constitution, shall be as valid against the United States under this Constitution, as under the Confederation.

Clause 2. Supreme law.

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any hing

in the Constitution or Laws of any State to the Contrary notwithstanding.

(g) Exemption for devices for investigational use. (1) It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

(2)(A) The Secretary shall, within the one hundred and twenty-day period beginning on the date of the enactment of this section [enacted May 28, 1976], by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 502, 510, 514, 515, 516, 519, or 706 [21 USCS §§ 352, 360, 360d, 360e, 360f, 360i, 376] or

subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

(B) The conditions prescribed pursuant to subparagraph (A) shall include the following;

(i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify.

(ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of data obtained as a result of

the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

(iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

(C) Procedures and conditions prescribed pursuant to subparagraph (A) for an exemption may appropriately vary depending on (i) the scope and duration of clinical testing to be conducted under such exemption, (ii) the number of human subjects that are to be involved in such testing, (iii) the need to permit changes to be made in the device subject to the exemption during testing conducted

in accordance with a clinical testing plan required under paragraph (3)(A), and (iv) whether the clinical testing of such device is for the purpose of developing data to obtain approval for the commercial distribution of such device.

(3) Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require, as a condition to the exemption of any device to be the subject of testing involving human subjects, that the person applying for the exemption --

(A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed clinical testing --

(i) to the local institutional review committee which has been established in accordance with regulations of the Secretary

to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted, or

(ii) to the Secretary, if --

(I) no such committee exists, or

(II) the Secretary finds that the process of review by such committee is inadequate (whether or not the plan for such testing has been approved by such committee),

for review for adequacy to justify the commencement of such testing; and, unless the plan and report are submitted to the Secretary, submit to the Secretary a summary of the plan and a report of prior investigations of the device (including, where appropriate, tests on animals);

(B) promptly notify the Secretary (under such circumstances and in such manner as the Secretary prescribes) of approval by a local institutional review committee of any clinical testing plan submitted to it in accordance with subparagraph (A);

(C) in the case of a device to be distributed to investigators for testing, obtain signed agreements from each of such investigators that any testing of the device involving human subjects will be under such investigator's supervision and in accordance with subparagraph (D) and submit such agreements to the Secretary; and

(D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, except where subject to such conditions as the Secretary may prescribe, the investigator

conducting or supervising the proposed clinical testing of the device determines in writing that there exists a life threatening situation involving the human subject of such testing which necessitates the use of such device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from his representative.

The determination required by subparagraph (D) shall be concurred in by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

4(A) An application, submitted in accordance with the procedures prescribed by regulations under paragraph (2), for an exemption for a device (other

than an exemption from section 516 [21 USCS § 360g]) shall be deemed approved on the thirtieth day after the submission of the application to the Secretary unless on or before such day the Secretary by order disapproves the application and notifies the applicant of the disapproval of the application.

(B) The Secretary may disapprove an application only if he finds the investigation with respect to which the application is submitted does not conform to procedures and conditions prescribed under regulations under paragraph (2). Such a notification shall contain the order of disapproval and a complete statement of the reasons for the Secretary's disapproval of the application and afford the applicant opportunity for an informal hearing on the disapproval order.

(5) The Secretary may by order withdraw an exemption granted under this subsection for a device if the Secretary determines that the conditions applicable to the device under this subsection for such exemption are not met. Such an order may be issued only after opportunity for an informal hearing, except that such an order may be issued before the provisions of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption with respect to which the order is to be issued will result in an unreasonable risk to the public health.

§360k. State and local requirements respecting devices

(a) **General rule**. Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --

(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

(b) **Exempt requirements**. Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if --

(1) the requirement is more stringent than a requirement under this Act which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement --

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this Act.

(June 25, 1938, ch 674, §521, as added May 28, 1976, P. L. 94-285, §2, 90 Stat. 574).

28 USCS § 1254

§ 1254. Courts of appeals; certiorari; appeal; certified questions

Cases in the court of appeals may be reviewed by the Supreme Court by the following methods:

(1) By writ of certiorari granted upon the petition of any party to any civil or criminal case, before or after rendition of judgment or decree;

Food and Drug Administration, HHS

PART 50-PROTECTION OF HUMAN SUBJECTS

Subpart A-General Provisions

Sec.

Subpart B-Informed Consent of Human Subjects

Subpart C-Protections Pertaining to Clinical Investigations Involving Prisoners as Subjects

50.46 Composition of institutional review boards where prisoners are involved.

50.48 Additional duties of the institutional review boards where prisoners are involved.

Subpart A-General Provisions

§50.1 Scope.

(a) This part applies to all clinical investigations regulated by the Food and Drug Administration under sections 505(i), 507(d), and 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Additional specific obligations and commitments of, and standards of conduct for, persons who sponsor or monitor clinical investigations involving particular test articles may also be found in other

parts (e.g., Parts 312 and 812). Compliance with these parts is intended to protect the rights and safety of subjects involved in investigations filed with the Food and Drug Administration pursuant to sections 406, 409, 502, 503, 505, 506, 507, 510, 513-516, 518-520, 706, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

[45 FR 36390, May 30, 1980; 46 FR 8979, Jan. 27, 1981]

§50.3 Definitions.

As used in this part:

(a) "Act" means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-902, 52 Stat. 1040 et seq. as amended (21 U.S.C. 321-392)).

(b) "Application for research or marketing permit" includes:

(1) A color additive petition, described in Part 71.

(2) A food additive petition, described in Parts 171 and 571.

(3) Data and information about substance submitted as part of the procedures for establishing that the substance is generally recognized as safe for use that results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in §§170.30 and 570.30.

(4) Data and information about a food additive submitted as part of the procedures for food additives permitted to be used on an interim basis pending additional study, described in §180.1.

(5) Data and information about a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in section 406 of the act.

(6) An investigational new drug application, described in Part 312 of this chapter.

(7) A new drug application, described in Part 314.

(8) Data and information about the bioavailability or bioequivalence of drugs for human use submitted as part of the procedures for issuing, amending, or repealing a bioequivalence requirement, described in Part 320.

(9) Data and information about an over-the-counter drug for human use submitted as part of the procedures for classifying these drugs as generally recognized as safe and effective and not misbranded, described in Part 330.

(10) Data and information about a prescription drug for human use submitted as part of the procedures for classifying these drugs as generally recognized as safe and effective and not misbranded, described in this chapter.

(11) Data and information about an antibiotic drug submitted as part of the procedures for issuing, amending,

or repealing regulations for these drugs, described in §314.300 of this chapter.

(12) An application for a biological product license, described in Part 601.

(13) Data and information about a biological product submitted as part of the procedures for determining that licensed biological products are safe and effective and not misbranded, described in Part 601.

(14) Data and information about an in vitro diagnostic product submitted as part of the procedures for establishing, amending, or repealing a standard for these products, described in Part 809.

(15) An "Application for an Investigational Device Exemption," described in Part 812.

(16) Data and information about a medical device submitted as part of the procedures for classifying these devices, described in section 513.

(17) Data and information about a medical device submitted as part of the procedures for establishing, amending, or repealing a standard for these devices, described in section 514.

(18) An application for premarket approval of a medical device, described in section 515.

(19) A product development protocol for a medical device, described in section 515.

(20) Data and information about an electronic product submitted as part of the procedures for establishing, amending, or repealing a standard for these products, described in section 358 of the Public Health Service Act.

(21) Data and information about an electronic product submitted as part of the procedures for obtaining a variance from any electronic products performance standard, as described in §1010.4.

(22) Data and information about an electronic product submitted as part of the procedures for granting,

amending, or extending an exemption from a radiation safety performance standard, as described in §1010.5.

(c) "Clinical investigation" means any experiment that involves a test article and one or more human suspects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i), 507(d), or 520(g) of the act, or is not ect to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of Part 58 of this chapter, regarding nonclinical laboratory studies.

(d) "Investigator: means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or

dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(e) "Sponsor" means a person who initiates a clinical investigation, but who does not actually conduct the investigation, i.e., the test article is administered or dispensed to or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., corporation or agency) that uses one or more of its own employees to conduct a clinical investigation it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

(f) "Sponsor-investigator"-means an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any

person other than an individual, e.g., corporation or agency.

(g) "Human subject" means an individual who is or becomes a participant in research, either as a recipient of the test article, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

(h) "Institution" means any public or private entity or agency (including Federal, State, and other agencies). The word "facility" as used in section 520(g) of the act is deemed to be synonymous with the term "institution" for the purposes of this part.

(i) "Institutional review board" (IRB) means any board, committee, or other group formally designated by an institution to review biomedical research involving humans as subjects, to approve the initiation of and conduct periodic review of such research. The term has the same

meaning as the phrase "institutional review committee" as used in section 520(g) of the act.

(j) "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statue, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(k) "Test article" means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n).

(l) "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

(m) "Legally authorized representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(secs. 406, 408, 409, 502, 503, 505, 506, 507, 510, 513-516, 518-520, 701(a), 706, and 801, 52 Stat. 1049-1053 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511-517 as amended, 72 Stat. 1785-1788 as amended, 74 Stat. 399-407 as amended, 76 Stat, 794-795 as amended, 90 Stat. 540-560, 562-574 (21 U.S.C. 346, 346a, 348, 352, 353, 355, 356,

357, 360, 360c-360f, 360h-360j, 371(a), 376, and 381); secs. 215, 301, 351, 354-360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 241, 262, 263b-263n))

[45 FR 36390, May 30, 1980 as amended at 46 FR 8950, Jan. 27, 1981; 54 FR 9038, Mar. 3, 1989]

Subpart B-Informed Consent of Human Subjects

§50.20 General requirements for informed consent.

Except as provided in §50.23, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or

the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

§50.21 Effective date.

The requirements for informed consent set out in this part apply to all human subjects entering a clinical investigation that commences on or after July 27, 1981.

§50.23 Exception from general requirements.

(a) The obtaining of informed consent shall be deemed feasible unless, before use of the test article (except as provided in paragraph (b) of this section), both the investigator and a physician who is not otherwise

participating in the clinical investigation certify in writing all of the following:

(1) The human subject is confronted by a life-threatening situation necessitating the use of the test article.

(2) Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.

(3) Time is not sufficient to obtain consent from the subject's legal representative.

(4) There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.

(b) If immediate use of the test article is, in the investigator's opinion, required to preserve the life of the subject, and time is not sufficient to obtain the independent determination required in paragraph (a) of this section in advance of using the test article, the determinations of the clinical investigator shall be made

and, within 5 working days after the use of the article, be reviewed and evaluated in writing by a physician who is not participating in the clinical investigation.

(c) The documentation required in paragraph (a) or (b) of this section shall be submitted to the IRB within 5 working days after the use of the test article.

§50.25 Elements of informed consent

(a) Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(2) A description of any reasonably foreseeable risks or discomforts to the subject.

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research

subjects' rights, and whom to contact in the event of a research-related injury to the subject.

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

(3) Any additional costs to the subject that may result from participation in the research.

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

(6) The approximate number of subjects involved in the study.

(c) The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective

(d) Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical

care to the extent the physician is permitted to do so under applicable Federal, State, or local law.

§50.27 Documentation of informed consent.

(a) Except as provided in §56.109(c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in §56.109(c), the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §50.25. This form may be read to the subject or the subject's legally authorized representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

(2) A "short form" written consent document stating that the elements of informed consent required by §50.25 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.

Medical Liability and Insurance Improvement Act of Texas, Tex.Rev.Civ. Stat.Ann. art. 4590i

Section 6.06. Consent to medical care that appears on the panel's list requiring disclosure shall be considered effective under this subchapter if it is given in writing, signed by the patient or a person authorized to give the consent and by a competent witness, and if the written consent specifically states the risks and hazards that are involved in the medical care or surgical procedure in the form and to the degree required by the panel under Section 6.04 of this subchapter.

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF TEXAS

HOUSTON DIVISION

CIVIL ACTION NO. H-86-381

NICK AND BARBARA LOZIER

Plaintiffs

VS.

F. BRANTLEY SCOTT, JR., M.D.

Defendant

JOINT PRETRIAL ORDER

Admissions of Fact

1. Dr. Scott surgically placed a "Hydroflex" penile prostheses in his patient, Nick Lozier, on or about January 24, 1984.

2. At the time of the surgery, the "Hydroflex" device had been approved by the federal Food and Drug Administration under its "investigative device exemption".

3. Dr. Scott was a founder and corporate director of American Medical Systems, the manufacturer of the "Hydroflex" prosthesis.

4. No special "Hydroflex" written consent form was signed with respect to the surgery Dr. Scott performed to implant the Hydroflex penile prostheses in Mr. Lozier.

BAYLOR COLLEGE OF MEDICINE

DEPARTMENT OF UROLOGY-713 791 4255

August 30, 1983

R. Thomas Solis, M.D.

Pulmonary Division

St. Luke's Episcopal Hospital

6720 Bertner

Houston, Texas 77030

Re: Project 510

Service Code U-74

Hydro-Flex Prothesis

Dear Dr. Solis:

I have revised the informed consent that was sent to you by Mark McIntyre from American Medical Systems. I have done this revision in consultation with Mr. McIntyre. The revision that I have made, I think, will be much clearer to the patient than what was previously submitted. I will be prepared to discuss

the project, as well as the informed consent, at the meeting scheduled for September 7.

Yours truly,

F. Brantley Scott, M.D.

FBS:jw

Enclosure

cc: Mark McIntyre - American Medical System.

BAYLOR

COLLEGE OF

MEDICINE

One Baylor Plaza

Houston, Texas

December 18, 1984

Teree Olson, R.N.

Clinical Research Associate

11001 Bren Road East

Minnetonka, MN 55343

Dear Ms. Olson,

The following Hydroflex patients have read and signed the Patient Informed Consent form.

Patient Name	D.O.S.
Lozier, Nick	01-24-84

Sincerely yours,

F. Brantley Scott, M.D.

Professor of Urology

FBS:kp

NO. 91-1064

IN THE

Supreme Court of The United States

OCTOBER TERM, 1991

NICK & BARBARA LOZIER,

Petitioners

v.

F. BRANTLEY SCOTT, JR., M.D.,

Respondent

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR RESPONDENT IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

ROBERT J. SWIFT,
Counsel of Record
DANIEL C. BROWN
Fulbright & Jaworski
1301 McKinney, Suite 5100
Houston, Texas 77010-3095
(713) 651-5151

Counsel for Respondent
F. BRANTLEY SCOTT, JR., M.D.

QUESTIONS PRESENTED FOR REVIEW

1. Whether the petitioners waived assertion of their informed consent claim, including federal regulations regarding informed consent, by voluntarily withdrawing their informed consent claim at trial and by failing to request jury submissions regarding informed consent.

2. Whether the petitioners waived any complaint regarding jury instructions by their failure to object at trial.

3. Whether, under Texas tort law, consent to the intentional tort of battery must be in writing.

4. In the alternative, assuming that the petitioners did not waive their informed consent claim, whether the State of Texas voluntarily incorporated 21 C.F.R. § 50.27 as the standard for documenting informed consent in medical liability cases.

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No. 91-1064

In The

Supreme Court of The United States

October Term, 1991

Nick & Barbara Lozier,

Petitioners

v.

F. Brantley Scott, Jr., M.D.,

Respondent

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR RESPONDENT IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

STATEMENT OF THE CASE

At the age of seventeen, Nick Lozier (plaintiff at trial, petitioner here) was involved in a serious automobile accident that crushed his pelvis and severed his urethra, resulting in urinary retention and diminished sexual function. Tr. vol. 16, p. 16-18, 93-94; vol. 19, p. 16. Periodic medical treatment was required after the accident to alleviate the effect of scar tissue blocking Mr. Lozier's urethra, which would leave him temporarily incontinent. Tr. vol. 16, p. 94. Eventually, a procedure performed by Dr. Ralph Hopkins in Wyoming rendered Mr. Lozier both incontinent and unable to obtain an erection. Tr. vol. 12, p. 403; vol. 17, p. 105; vol. 19, p. 19-25. Mr. Lozier conceded at trial that he was unable to obtain an erection following the procedure by Dr. Hopkins. Tr. vol. 17, p. 103-105.

Mr. Lozier was referred by Dr. Hopkins to Dr. F. Brantley Scott, Jr. (defendant at trial, respondent here), now deceased, in Houston, Texas for treatment of both urinary incontinence and impotence. Tr. vol. 11, p. 282; vol. 17, p. 123; vol. 19, p. 45. Dr. Scott was to implant an artificial urinary sphincter to give Mr. Lozier control of his urine and also agreed to evaluate Mr. Lozier for implantation of an inflatable penile prosthesis (the Hydroflex) to enable Mr. Lozier to obtain an erection. Tr. vol. 10, p. 92.

Dr. Scott obtained Mr. Lozier's consent for implantation of the Hydroflex penile prosthesis after discussing the procedure with him in detail on several occasions. Tr. vol. 10, p. 92; vol. 12, p. 324-330; vol. 17, p. 193-197. On January 24, 1984, after Mr. Lozier had been pre-medicated for surgery, the charge nurse informed Dr. Scott that a consent form for the Hydroflex procedure had not been signed. Tr. vol. 12, p. 330-331. To avoid the risks inherent in a second surgery, and because Mr. Lozier had stated his consent for the penile prosthesis, Dr. Scott notated in the medical chart acknowledgment that informed consent had been obtained and proceeded with the surgery. Tr. vol. 12, p. 332.

Nick and Barbara Lozier (Nick's wife) brought this action against Dr. Scott pursuant to Texas law alleging battery, lack of informed consent and negligent pre-surgical work-up. Joint Pre-trial Order, Tr. vol. 3, tab 21. The federal district court obtained jurisdiction to preside over the case because the parties were in complete diversity. 28 U.S.C. § 1332. *See,* Tr. vol. 3, tab 21, p. 373. The Loziers also brought suit against Dr. Ralph Hopkins in Wyoming state court. The Loziers claimed, in the alternative, that Dr. Hopkins and Dr. Scott each caused Mr. Lozier's impotence. Tr. vol. 17, p. 105, 111.

The Loziers' claim against Dr. Hopkins was dropped because limitations barred recovery against him and the

Loziers proceeded only against Dr. Scott. Tr. vol. 18, p. 260. However, before dismissing his claim against Dr. Hopkins, Mr. Lozier executed an affidavit that was filed in the Wyoming state court. In his sworn affidavit, Mr. Lozier claimed he was *rendered impotent by Dr. Hopkins' treatment* (which *preceded* treatment by Dr. Scott). Tr. vol. 17, p. 114, 214; vol. 18, p. 253. This admission by Mr. Lozier proved ruinous to his case against Dr. Scott. The very foundation of Mr. Lozier's claim was that he *was not impotent* prior to treatment by Dr. Scott and, therefore, would not have consented to implant of a penile prosthesis. *See e.g.,* Tr. vol. 17, p. 83-89.

As evidence was presented, it became apparent that this was not an informed consent case. Mr. Lozier's position was not that he would not have consented to implant of the penile prosthesis had he been apprised of some undisclosed risk (informed consent), but that he was not impotent and did not consent to the implant, which would constitute a battery under Texas law. Tr. vol. 16, p. 48-52.

After the close of the Loziers' case, Dr. Scott presented the court with a motion for directed verdict, arguing that the elements of an informed consent cause of action were not present. Tr. vol. 21, 2-3. In response, the Loziers voluntarily withdrew their informed consent claim and agreed to proceed with only battery and negligent presurgical work-up. Tr. vol. 21, p. 5. The Loziers did not request that questions to support recovery for lack of informed consent be submitted to the jury.

At the close of the evidence, the district court correctly instructed the jury that Texas civil battery law did not require that consent be in writing. After deliberation, the jury found that Mr. Lozier did consent to implantation of the Hydroflex prosthesis and that Dr. Scott was not negligent in his pre-surgical work-up. Tr. vol. 1, tab 81. All other jury

interrogatories were conditioned upon a finding of negligence or of no consent and were therefore not answered by the jury. The district court entered judgment for Dr. Scott based upon the jury verdict and the Loziers appealed to the United States Court of Appeals for the Fifth Circuit. The Fifth Circuit affirmed in an unpublished opinion. Petition for Writ of Certiorari, Appendix No. 1.

SUMMARY OF THE ARGUMENT

A petition for writ of certiorari is to be granted only if special and important reasons therefor exist. SUP. CT. R. 10.1. The petitioners assert that an important question of federal law exists pursuant to Rule 10.1(c), believing that the concept of federal preemption somehow imposes upon the states the duty to provide civil tort recovery for failure to comply with Federal Food and Drug Administration (FDA) regulations. Fortunately, however, the doctrine of federal preemption does not operate to so pervasively usurp the historic right of the states to govern civil tort recovery for claims brought under state law. Therefore, resolution of the relevant issues in this diversity case involves interpretation of a Texas statute, the Texas Medical Liability and Insurance Improvement Act, TEX. REV. CIV. STAT. art. 4590i. Because state law, and not federal law, controls in this case, there is no basis for review by this Court. SUP. CT. R. 10.1.

At trial, the Loziers voluntarily withdrew their informed consent claim and proceeded against Dr. Scott with only battery and negligent pre-surgical work-up claims. As a result, this was no longer an informed consent case and no informed consent provision, whether originating under federal or state law, remained applicable. In particular, whether a writing was required to document informed consent pursuant to federal regulation had no bearing on this case. The

only remaining issue was whether oral consent was a sufficient defense in Texas to the intentional tort of battery.

The Loziers brought this diversity action under Texas tort law. If the Loziers had not dropped their informed consent claim, the issue in this case would have been whether a plaintiff could recover *under Texas tort law* for the defendant's failure to comply with the writing requirement contained in 21 C.F.R. § 50.27. Stated more specifically, the question to be decided would have been whether Texas informed consent law voluntarily incorporated 21 C.F.R. § 50.27 as a basis for tort recovery. Because the Loziers did withdraw their informed consent claim, however, the issue at trial was whether Texas *battery* law required that consent be in writing to be effective.

The Loziers have mischaracterized Dr. Scott's position in this case as, "[T]he subject may give his informed consent orally" pursuant to FDA regulations, particularly 21 C.F.R. § 50.27. Petition, p. 17. On the contrary, there is no doubt that 21 C.F.R. § 50.27 requires that informed consent for implantation of investigational devices be documented in writing. However, this case was not an administrative proceeding to enforce compliance with FDA regulations. Therefore, Dr. Scott's failure to comply with 21 C.F.R. § 50.27 was not dispositive.

The Loziers still maintain that Dr. Scott's position that FDA regulations do not obligate the states to provide for tort recovery for violation of 21 C.F.R. § 50.27 "render[s] the express words of 21 U.S.C. § 360j(g) and 21 C.F.R. § 50.27(a) utterly meaningless." Petition, p. 29. However, the regulations neither create a federal cause of action, nor obligate the states to provide one. The goal for involvement in the investigational process is FDA approval of the particular device. Failure to comply with the FDA regulations, including 21 C.F.R. § 50.27, can result in withdrawal of the

investigational device exemption, an administrative remedy. 21 C.F.R. § 812.30(b)(4). Therefore, failure to document informed consent in writing could frustrate FDA approval of the device. The absence of a state tort remedy for failure to comply with these regulations does not hinder the FDA's ability to enforce compliance with its rules. Therefore, the doctrine of federal preemption simply does not apply and the requisites for review by this Court do not exist in this case.

ARGUMENT AND AUTHORITIES

I. FDA Regulations Governing Informed Consent For Investigational Devices Are Not Relevant To This Case Because The Petitioners Voluntarily Withdrew Their Informed Consent Claim At Trial.

There is a fundamental distinction between a cause of action for battery, which is an intentional tort, and a cause of action for lack of informed consent, which is founded in negligence. *See, Wilson v. Scott*, 412 S.W.2d 299, 302 (Tex. 1967). An informed consent claim is based upon failure to reasonably disclose the material risks of a procedure. *Jones v. Papp*, 782 S.W.2d 236, 241 (Tex. App. — Houston [14th Dist.] 1989, writ denied). The emphasis in informed consent cases is whether disclosure was adequate. *Karp v. Cooley*, 493 F.2d 408, 419-420 (5th Cir.), *cert. denied*, 419 U.S. 445 (1974). All actions for informed consent in Texas are governed by the Texas Medical Liability and Insurance Improvement Act, TEX. REV. CIV. STAT. art. 4590i (the "Texas Medical Liability Act"). The Medical Liability Act, in conjunction with the case law, establishes the elements which a plaintiff must prove to recover for lack of informed consent.

The elements of the intentional tort of battery, on the other hand, are established by the common law of Texas. For

there to be a battery, there must be an intentional act. RESTATEMENT (SECOND) OF TORTS § 13. There can be no battery if the actor was merely negligent. RESTATEMENT (SECOND) OF TORTS § 18(2). Under Texas law, consent is an absolute defense to the intentional tort of battery.[1] RESTATEMENT (SECOND) OF TORTS § 13, Comment B (1965); *Moss v. Rishworth*, 222 S.W. 225, 226 (Tex. Comm'n App. 1920, holding approved). There is no requirement that consent be in writing and oral consent to surgery is an effective defense against a claim of battery. *See, Gravis v. Physicians and Surgeons Hosp. of Alice*, 427 S.W.2d 310, 311 (Tex. 1968).

During trial, in response to a motion for directed verdict by Dr. Scott, the Loziers voluntarily withdrew their assertion of an informed consent cause of action and agreed to proceed with only their battery and negligent pre-surgical work-up claims. Tr. vol. 11, p. 235; vol. 21, p. 5. The Loziers withdrew informed consent because the facts did not support its submission to the jury. Even Mr. Lozier admitted to discussing the risks of the procedure with Dr. Scott in detail. Tr. vol. 17, p. 193-197. No testimony was presented that a material risk of the penile implant procedure was withheld from Mr. Lozier. Rather, Mr. Lozier claimed that he was not impotent and, therefore, did not consent to the procedure, which would constitute a battery under Texas law.

During final argument, the Loziers reaffirmed that withdrawal of their informed consent claim had been voluntary. Mr. Robert J. Swift (Dr. Scott's attorney) commented to the jury that the issue of informed consent had been resolved by

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[1] The Loziers' assertion that consent is an *affirmative* defense to battery, however, is not correct. *See* Petition, p. 28. Lack of consent is an element which the plaintiff must establish as part of his *prima facia* case. *Gravis v. Physicians and Surgeons Hosp. of Alice*, 427 S.W.2d 310, 311 (Tex. 1968).

the court. Mr. Arnold Vickery, an attorney for the Loziers, objected to Mr. Swift's characterization, stating that the informed consent issue "*was resolved by* ***us***." Tr. vol. 22, p. 2 (emphasis added). The court sustained Mr. Vickery's objection, explaining that the court "directed the verdict because [the Loziers] withdrew their claim." Tr. vol. 22, p. 2. Therefore, only battery and negligent pre-surgical work-up were submitted to the jury. The Loziers never requested that issues supporting recovery under an informed consent theory be submitted.[2]

Withdrawal of the Loziers' informed consent claim rendered both federal and state law regarding informed consent immaterial to this case and waived any error on appeal. FED. R. CIV. P. 61. The petitioners make a tortured attempt in their petition for writ of certiorari to tie a FDA regulation governing documentation of informed consent for implantation of investigational devices (21 C.F.R. § 50.27) to the elements of the intentional tort of *battery*. However, the Loziers waived any assertion of the FDA regulation that expressly governs documentation of *informed consent* by failing to preserve an informed consent claim at trial. Therefore, the only remaining issue at trial was whether oral consent was sufficient in Texas to avoid liability for a battery. Both the federal district court and the Fifth Circuit Court of Appeals held that oral consent to a battery was

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[2] The jury was asked, "Do you find by a preponderance of the evidence that Dr. F. Brantley Scott implanted a 'Hydroflex' penile prosthesis in Mr. Lozier without the consent of Mr. Lozier?" and "Do you find by a preponderance of the evidence that Dr. F. Brantley Scott was negligent in his preoperative work-up of Mr. Lozier?" Tr. vol. 1, tab 81. The jury answered "No" to both issues. The sufficiency of the evidence to support the jury's findings has not been challenged by the Loziers on appeal.

sufficient under Texas law. This leaves no "important question of federal law" to be decided by this Court. SUP. CT. R. 10.1(c).

II. The Petitioners Waived Any Claim Of Error Regarding Jury Instructions.

In one question presented for review, the Loziers assert that this Court should determine, "[W]hether the District Court erred in refusing to instruct the jury on the provisions of federal law . . .". Petition, p. ii. However, the record does not establish that the Loziers ever requested the district court to so instruct the jury.[3] Therefore, the Lozier's have waived any error regarding jury instructions on appeal.

The Loziers had the burden to provide the United States Court of Appeals for the Fifth Circuit with sufficient record to establish that error was committed and properly preserved at trial. FED. R. APP. P. 10(b)(1); *Smith v. United States*, 343 F.2d 539, 541 (5th Cir.), *cert. denied*, 382 U.S. 861 (1965). In the absence of sufficient transcript to affirmatively establish that error was committed and properly preserved, the Fifth Circuit had "no alternative but to affirm the decision of the district court." *McDonough Marine Serv., Inc. v. M/V Royal Street*, 608 F.2d 203, 204 (5th Cir. 1979).

In particular, to complain of error regarding jury instructions or interrogatories, the record on appeal must establish that the petitioners properly and timely objected to the jury charge at trial. FED. R. CIV. P. 51; *Farrar v. Cain*, 756 F.2d 1148, 1150 (5th Cir. 1985). Since the record in this case does not establish that the Loziers objected to the charge, the

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[3] The Loziers resisted providing even as much of the transcript as was available. It was upon motion by Dr. Scott, which the Loziers opposed, that any record other than limited excerpts of Dr. Scott's testimony were included. *See* Tr. vol. 1, tabs 104, 105, 107 and 109.

Fifth Circuit had to presume that no such objections were made. FED. R. CIV. P. 51. Therefore, even if writ of certiorari were granted, this Court could not consider whether the court's charge was appropriate. Because the Loziers failed to properly preserve error, the criteria for review by this Court have not been met. SUP. CT. R. 10.1.

III. The Doctrine Of Federal Preemption Is Not Applicable To This Case.

Because the Loziers did not plead a federal cause of action (Joint Pre-trial Order), Texas substantive law applies in this diversity case. *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938). It is unusual that the Loziers, who were the plaintiffs at trial, would argue that a federal regulation preempted the state law under which they brought their claim. If, as the Loziers assert, federal regulations preempted Texas tort law, the state law under which the Loziers brought their claim would be nullified. *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 712-713 (1985). The result would be dismissal of their claim. *See, Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 244 (5th Cir. 1989).

As discussed *Infra* ¶ I, the Loziers voluntarily withdrew their informed consent claim at trial and made no request that interrogatories regarding informed consent be submitted to the jury. By withdrawing their informed consent claim, the Loziers waived assertion of any regulation regarding informed consent. However, the federal regulation which the Loziers now assert provides that a patient's informed consent for the implantation of an investigational device must be document in writing. Although withdrawal of their informed consent claim at trial defeats the Loziers' position on appeal, to fully brief all hypothetical issues, it will be presumed in this section that the Loziers did not waive their informed consent claim and that informed consent interrogatories were submitted for jury consideration.

Congress provided the preemption test for the regulation asserted by the Loziers (21 C.F.R. § 50.27) in 21 U.S.C. § 360k(a). *See, Smith v. Pingree*, 651 F.2d 1021, 1022-23 (5th Cir. 1981). Section 360k(a) is an express statement by Congress regarding the extent to which state law is preempted by the pertinent federal regulation. The courts look to other indicia of Congress' intent regarding preemption only in the absence of express language. *Hillsborough County*, 471 U.S. at 713.

Congress has provided that:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any *requirement* —
>
> (1) which is *different from, or in addition to*, any requirement applicable under this chapter to the device, *and*
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added). Therefore, Congress intended only to preempt "different" or "additional" "requirements" promulgated by the states. Section 360k(a) does not impose upon the states an obligation to provide for tort recovery for violations of federal regulations.

The Federal Food, Drug and Cosmetic Act (FDCA) was promulgated in part to establish guidelines for FDA investigation and approval of medical devices. 21 U.S.C. § 360j(g)(1). Regulations established pursuant to the FDCA detail the administrative procedure for the investigational process. One such regulation, 21 C.F.R. § 50.27, requires that informed consent for medical implant procedures be documented in writing. The Loziers sought to introduce a

copy of the 1989 version of 21 C.F.R. § 50.27 into evidence as PX63.[4] Tr. vol. 10, p. 110.

The goal for involvement in the investigatory process is ultimate FDA approval of the particular medical device. Failure to comply with the federal regulations, including 21 C.F.R. § 50.27, can result in withdrawal of the investigational device exemption, thereby defeating efforts to obtain FDA approval of the device. 21 U.S.C. § 360j(g)(5); 21 C.F.R. § 812.30(b)(4).[5] The absence of a tort remedy for failure to comply with the regulations does not impede the FDA's ability to enforce compliance with its rules. Therefore, although Texas could perhaps voluntarily incorporate FDA "standards" as a basis of tort recovery, its failure to do so does not create *requirements* that are *additional to* or *different from* those imposed by the FDA.

There is no conflict between 21 C.F.R. § 50.27 and Texas tort law and, therefore, the doctrine of federal preemption does not apply to this case. Compliance with the federal regulation was (and is) entirely consistent with Texas law. The federal regulation asserted by the Loziers, 21 C.F.R. § 50.27, required that informed consent for the implantation of investigational devices be documented in writing. Texas tort law neither required nor discouraged written documentation of informed consent. *See Infra* ¶ IV(B). Texas law simply did not provide for tort recovery for a physician's failure to comply with 21 C.F.R. § 50.27. Therefore, state

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[4] PX63 was not relevant becasue the event occurred in 1984, rather than 1989, and because the Loziers had withdrawn their informed consent claim. *Infra* ¶ I. The exhibit was offered for impeachment purposes only (Tr. Vol. 10, p. 128-129) and the attorney representing the Loziers was permitted to read the regulation to the jury. Tr. Vol. 10, p. 136-137.

[5] An investigational device exemption can be withdrawn or withheld if there is "reason to believe . . . informed consent is inadequate. . . ." 21 C.F.R. § 812.30(b)(4).

law did not create a requirement that was in addition to or different from the federal requirement regarding the documentation of informed consent and the doctrine of federal preemption did not apply.

Because the only relevant issue to be decided involved the interpretation of Texas law, the requirements of SUP. CT. R. 10.1, which provides the criteria for review on writ of certiorari, have not been met.

IV. The Pertinent Issue On Appeal Was Whether Texas Law Voluntarily Incorporated Federal Regulations As The Basis For Tort Recovery In Medical Liability Cases.

A. *Battery*

The Loziers assert that Dr. Scott should be liable under a theory of "battery *per se*" for failure to comply with an FDA regulation requiring that informed consent for investigational devices be documented in writing. Even though the jury found that Mr. Lozier consented to the procedure, the Loziers argue that Dr. Scott should be liable for battery as a matter of law for his failure to get a form signed documenting that consent.[6]

Under appropriate circumstances, the states may incorporate federal regulations as standards for tort recovery. As previously discussed *Infra,* ¶ III, however, the states are not compelled to do so. Therefore, the relevant issue on appeal was whether Texas law voluntarily incorporated the federal regulation asserted by the Loziers, 21 C.F.R. § 50.27, as the basis for tort recovery in medical malpractice actions. The federal district court's determination, which was entitled to

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[6] The sufficiency of the evidence to support the jury's finding that Mr. Lozier consented to the procedure has not been contested by the Loziers on appeal.

deference on appeal, was that Texas law did not. *See, Freeman v. Continental Gin Co.*, 381 F.2d 459, 466 (5th. Cir. 1967).

There has never been application in Texas of the negligence *per se* doctrine to an intentional tort.[7] The concept of negligence *per se* allows the courts to substitute a statutory "standard" for a jury determination of what the ordinarily prudent person would do under the circumstances. *Nixon v. Mr. Property Management Co., Inc.*, 690 S.W.2d 546, 549 (Tex. 1985). No "standard" of conduct is applicable, however, to an intentional tort such as battery. With an intentional tort, the actor's conduct is not compared against the "ordinarily prudent person". If the actor intended the offensive touching and the recipient did not consent, the actor is liable for battery regardless of what an "ordinarily prudent person" would have done. Therefore, application of the negligence *per se* doctrine to an intentional tort such as battery just simply does not fit.

B. *Informed Consent*

The Texas Medical Liability and Insurance Improvement Act created a Medical Disclosure Panel that has the duty to classify various surgical procedures into two categories: those requiring disclosure of risks (List A) and those requiring no disclosure (List B). TEX. REV. CIV. STAT. art. 4590i, § 6.04. If a procedure is classified under List A, the physician is required to disclose those risks the Panel determined to be material. TEX. REV. CIV. STAT. art. 4590i, § 6.05. If the specified disclosure is made in writing for List A procedures, a rebuttable presumption is created that disclosure was adequate. TEX. REV. CIV. STAT. art. 4590i, § 6.07(a).

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[7] In addition, no Texas case has ever applied the concept of negligence *per se* to an informed consent action.

In 1984, implantation of an inflatable penile prosthesis such as the Hydroflex device had not been classified by the Texas Medical Disclosure Panel and therefore was not contained on either List A or List B. Texas Medical Disclosure Panel, 7 Tex. Reg. 3473 (Sept. 24, 1982).[8] No presumption was created by written disclosure, or the lack thereof, if the procedure was one that has not yet been classified by the Panel. *Barclay v. Campbell,* 704 S.W.2d 8, 9 (Tex. 1986). Therefore, the provision cited as authority by the Loziers on page 23, footnote 4 of their petition to this Court is misleading. Section 6.06 of the Texas Medical Liability Act did not apply to this case because, in 1984, the procedure performed by Dr. Scott did not appear on the Panel's list requiring disclosure.[9]

The Medical Liability Act imposes the "duty otherwise imposed by law" upon physicians obtaining a patient's informed consent where the procedure has not yet been classified by the Medical Disclosure Panel. TEX. REV. CIV. STAT. art. 4590i, § 6.07(b). The Loziers argue that this language incorporates federal regulations as the criteria for documenting informed consent. However, the Texas Supreme Court has held that the phrase "duty otherwise imposed by law" in Section 6.07(b) simply refers to the duty imposed by Section 6.02 of the Medical Liability Act: "To disclose all risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." *Peterson v. Shields,* 652 S.W.2d 929, 931 (Tex.

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[8] The list applicable to this case was effective beginning January 1, 1983. 7 Tex. Reg. 3453 (Sept. 24, 1982). The next revision to the list was not effective until January 1, 1985. 25 TEX. ADMIN. CODE § 601.1.

[9] In addition, documenting informed consent in writing only creates a rebuttable presumption that informed consent was obtained, even for those procedures on the Medical Disclosure Panel's list requiring disclosure. TEX. REV. CIV. STAT. art 4590i, § 6.07(a).

1983). Since the Texas Supreme Court is the highest authority regarding construction of Texas statutes *(Murdock v. City of Memphis,* 87 U.S. (20 Wall.) 590, 633 (1874)), this Court is not entitled to reinterpret Article 4590i. The considerations governing review on petition for writ of certiorari have not been met in this case because the relevant issue on appeal was interpretation of a Texas statute. SUP. CT. R. 10.1.

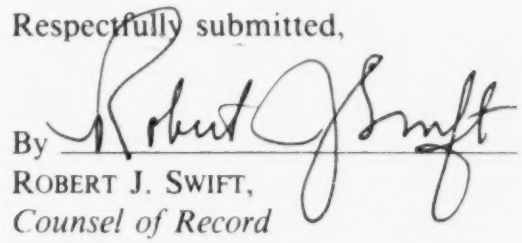
CONCLUSION

The concept of federal preemption is not relevant to this case. Texas law does not create a requirement that is different from or additional to FDA regulations simply because there is no recovery under Texas tort law for failure to comply with the federal regulation. *See,* 21 U.S.C. § 360k(a). In addition, the doctrine of federal preemption would operate to nullify the basis of the Loziers' claim, resulting in dismissal of their case against Dr. Scott, since their claim was brought pursuant to Texas tort law. Therefore, the relevant issue on appeal was whether Texas tort law voluntarily incorporated the relevant FDA regulations as the basis of tort recovery in medical malpractice cases. Resolution of that issue required interpretation of the Texas statute under which the Loziers brought their claim.

Both the Federal District Court for the Southern District of Texas and the Fifth Circuit Court of Appeals held that Texas law did not incorporate 21 C.F.R. § 50.27, the federal regulation asserted by the Loziers, as the basis for tort recovery in medical malpractice cases. The guidelines delineated in Rule 10.1 of the Rules of the Supreme Court for granting review on writ of certiorari have not been met. Because there is no important question of federal law for this Court to consider, Respondent F. Brantley Scott, Jr., M.D., deceased,

respectfully prays that this court deny the Lozier's Petition for Writ of Certiorari.

Respectfully submitted,

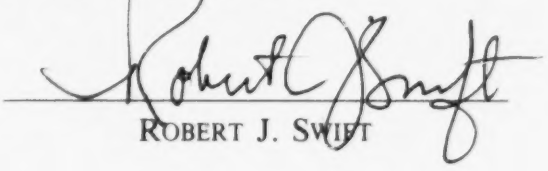
By 

ROBERT J. SWIFT,
Counsel of Record
DANIEL C. BROWN
Fulbright & Jaworski
1301 McKinney, Suite 5100
Houston, Texas 77010-3095
Telephone: 713/651-5151
Telecopier: 713/651-5246

Counsel for Respondent
F. BRANTLEY SCOTT, JR., M.D.

CERTIFICATE OF SERVICE

Pursuant to Rule 29 of the Rules of the Supreme Court of the United States, I certify that three copies of the Brief for Respondent have been served on Arnold Anderson Vickery, Vickery, Kilbride, Gilmore & Vickery, 2929 Allen Parkway, Suite 2770, Houston, TX 77019 via first-class postage prepaid, on this 21 day of January, 1992.



ROBERT J. SWIFT